K041520

SEP - 3 2004

Mantra International Ltd.
P.O. Box 800
Oxford, OH 45056
Tel: (740) 549-5703
FAX: (740) 549-5701

510(k) Summary

Contact Person: Brent Reider

Date of Preparation: March 12, 2004

Trade Name: Mantra TENS Model NT3

Common Name: Transcutaneous Nerve Stimulator

Classification Name: Stimulator, Nerve, Transcutaneous, for Pain Relief

Product Code: GZJ

Regulation Class: 2

Regulation Number: 882.5890

Description of the Device: The Mantra TENS Model NT3 is a Dual Channel Transcutaneous Nerve Stimulator (TENS).

Intended Use: The device is intended for the symptomatic relief of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

Technical Characteristics: The technical characteristics of the Mantra TENS Model NT3 are identical to the predicate device. The unit is battery operated and produces a biphasic asymmetrical waveform. This is a digital unit, which provides twelve pre-set programs and two user-customized programs. The electrodes consist of hydrogel in contact with the skin, a carbon conductor, and a nonwoven backing material.

There are three modes of operation: Conventional TENS, Burst Mode, and Modulation.

The Conventional TENS mode enables the user to select any rate between 2 Hz – 200 Hz, and a pulse width between 50 – 300 microseconds. This is the most frequently used of the three modes. The most common selection is 80 Hz with a 200 microsecond pulse width.

The burst mode is comparable to the low rate TENS technique except that each low rate pulse is substituted for by a short BURST of 9 pulses [200 microseconds] at 150 Hz.

The modulation mode is achieved by continuously cycling the pulse width and rate.

Substantial Equivalence: This product is substantially equivalent to the Classic TENS™ manufactured by Care Rehab, McLean, Virginia (K020437).

Substantial equivalence is based upon:

- The Mantra TENS Model NT3 has the same indications for use as the predicate device.
- The Mantra TENS Model NT3 has equivalent technological characteristics and instructions for use, as compared to the predicate device.
- The device meets the mandatory performance standards.
- The biocompatibility of the electrodes has been established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 - 2004

Mantra International Ltd.
C/o Mr. Robert B. Spertell
RBS Technologies, LLC
10235 Glade Avenue
Chatsworth, California 91311

Re: K041520
Trade/Device Name: Mantra TENS Model NT3
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: March 9, 2004
Received: June 7, 2004

Dear Mr. Spertell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Mantra TENS Model NT3

Indications for Use: TENS is used for symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

Prescription Use ___X___ AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041520
MNM